

CLAIMS

1. Transdermal therapeutic system, comprising a backing layer inert to the components of the matrix, a self-adhesive matrix layer containing (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]amino]-1-naphthalenol in an effective amount and a protective foil or sheet to be removed prior to use, characterised by a matrix that is based on a non-aqueous, acrylate-based or silicone-based polymer adhesive system having a solubility of $\geq 5\%$ (w/w) for (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]-amino]-1-naphthalenol, and said matrix is substantially free of inorganic silicate particulates.

2. Transdermal therapeutic system according to claim 1 that contains $<0.5\%$ (w/w) inorganic silicate particulates.

3. Transdermal therapeutic system according to claim 1 that contains $<0.05\%$ (w/w) inorganic silicate particulates.

4. Transdermal system according to claim 1 in which the acrylate-based polymer adhesive contains at least two of the following monomers: acrylic acid, acrylamide, hexylacrylate, 2-ethylhexylacrylate, hydroxyethylacrylate, octylacrylate, butylacrylate, methylacrylate, glycidylacrylate, methacrylic acid, methacrylamide, hexylmethacrylate, 2-ethylhexylmethacrylate, octylmethacrylate, methylmethacrylate, glycidylmethacrylate, vinylacetate or vinylpyrrolidone.

5. Transdermal system according to claim 1 in which the silicone-based polymer adhesive includes additives to enhance the solubility of (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thi nyl)ethyl]amino]-1-naphthalenol in the form of hydrophilic polymers or glycerol or glycerol derivatives.

6. Transdermal system according to claim 4 or 5 in which (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]-amino]-1-naphthalenol is contained in the acrylate-based polymer adhesive in a concentration of from 10 to 40% (w/w), or in the silicone-based polymer adhesive in a concentration of from 5 to 25% (w/w).

7. Transdermal system according to claim 6 that contains substances that enhance the permeation of (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]amino]-1-naphthalenol into the human skin.

8. Transdermal system according to claim 7 in which the permeation-enhancing substance is selected from the group of fatty alcohols, fatty acids, fatty acid esters, fatty acid amides, glycerol or its derivatives, N-methylpyrrolidone, terpenes or terpene derivatives.

9. Transdermal system according to claim 8 in which the permeation-enhancing substance is oleic acid or oleyl alcohol.

10. Transdermal system according to claim 5, in which the hydrophilic polymer is polyvinylpyrrolidone, a copolymer of vinylpyrrolidone and vinylacetate, polyethyleneglycol, polypropylene glycol or a copolymer of ethylene and vinylacetate.

11. Transdermal system according to claim 10 wherein the hydrophilic polymer is soluble polyvinylpyrrolidone being present in the active substance-containing matrix layer at a concentration of 1.5 - 5% (w/w).

12. Transdermal system according to claim 1 in which the matrix contains inert fillers to improve cohesion.

13. A process for preparing a transdermal therapeutic system, comprising the following steps:

- i) mixing a suspension of (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]amino]-1-naphthalenol hydrochloride in ethanol with an alkaline compound in ethanol to convert the hydrochloride into the free base,
- ii) optionally filtering the resultant suspension,
- iii) adding polyvinylpyrrolidone and a solution of an adhesive, and iv) drying the product.

14. A process according to claim 13 wherein, as alkaline compound, sodium hydroxide or potassium hydroxide are used.

15. A process according to claim 13 wherein, as alkaline compound, sodium metasilicate or potassium metasilicate, or sodium or potassium trisilicate are used.

16. The process of claim 13 wherein before drying the product, the mixture is spread on an inert backing layer or protective foil or sheet in such a manner as to produce a uniform film.

17. A product prepared by a process according to one of the claims 13 to 16.

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